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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/518,554	03/03/2000	Jacob Vroman	AIMPORT.011A	7420

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	**PAPER NUMBER**
1615	14

DATE MAILED: 12/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/518,554	VROMAN, JACOB	
	Examin r	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

Prosecution on the merits of this application is reopened on claims 23-45 considered unpatentable for the reasons indicated below:

The instant invention is rendered clearly obvious to one of ordinary skill in the art, given the teachings of US 6,146,664 (Siddiqui), US 5,843,411 (Hernandez et al.) and US 5,308,621 (Taylor et al.).

Applicant is advised that the Notice of Allowance mailed 04/24/03 is vacated. If the issue fee has already been paid, applicant may request a refund or request that the fee be credited to a deposit account. However, applicant may wait until the application is either found allowable or held abandoned. If allowed, upon receipt of a new Notice of Allowance, applicant may request that the previously submitted issue fee be applied. If abandoned, applicant may request refund or credit to a specified Deposit Account.

Claims 23-45 are pending. Claims 23-45 are rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 23-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siddiqui (US Pat. No. 6,146,664).

Siddiqui teaches an ascorbic acid – (Vitamin C) composition in a non-aqueous or substantially anhydrous silicone vehicle having superior stability, a high degree of bioavailability and effectiveness, for example in topical applications to reduce wrinkles and increase collagen growth and elasticity, whereby the ascorbic acid is contained in an amount of 0.1% to 40% by weight (see Abstract); (column 2, line 45 – col. 4, line 25); Tables and Examples. A method of improving skin appearance using the ascorbic acid (Vitamin C) composition is also taught.

According to Siddiqui, the solid ascorbic acid is substantially completely insoluble in the silicone-based vehicle, and the vehicle provides an ideal reservoir for delivering the ascorbic acid into the skin where it is soluble in the moisture-laden levels of the skin. It has been unexpectedly found that the combination of the solid ascorbic acid dispersed in the silicone-based vehicle delivers the intended effect on the skin while simultaneously being safe and effective (col. 2, lines 48-60).

Siddiqui teaches that the particulate ascorbic acid consists essentially of solid ascorbic acid particles having a particle size of less than about 20 microns (μm), for example less than about 12 (μm) (instant claims require no greater than ~5(μm)) (col. 3, lines 52-54). The preparation also contains materials, such as other vitamins, cosmetic and herbal ingredients and/or medicaments as desired (col. 2, lines 64-67).

The examples demonstrate various preparations comprising ascorbic acid. For instance, Table 2 exemplifies a method of making the ascorbic acid preparation by combining Polysilicone 11, dimethicone, cyclomethicone, tocopheryl acetate and retinyl palmitate whereby solids of ascorbic acid are dispersed into this mixture with appropriate agitation. The ascorbic acid is ground into the mixture using a three-roll mill to obtain a solids ascorbic acid particle size of less than 12.5 microns. Alternative procedures are also disclosed.

Siddiqui is silent with respect to the *pH* of the ascorbic acid composition. However, Siddiqui does teach that the ascorbic acid composition is in a silicone-based, non-aqueous vehicle wherein the ascorbic acid is not solubilized and the pH may be close to neutral (see col. 2, lines 52-56). The similarities to the process of making the prior art's composition and the claimed invention is noted in that the instant application teaches that the L-ascorbic acid powder is particulate and can be prepared by grinding, etc., in the absence of any teachings for positive steps to alter the pH of the solid ascorbic acid (see pg. 4, lines 6+ of the instant application). Note that Siddiqui uses ascorbic acid as Vitamin C (Abstract and column 1, lines 6 and 13). As such, the ascorbic acid taught by Siddiqui is L-ascorbic acid.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to provide UV protection or treat wrinkles or to stimulate collagen production in a mammal by topically applying a Vitamin C composition of Siddiqui having at least 30% L-ascorbic acid, by weight, and a non-aqeous carrier, since Siddiqui discloses that his formulation that contains 0.1% to 40% or higher has been found to have a high degree of bioavailability and effectiveness as a topical application with the expectation of successful treatment or therapy, as similarly desired by the applicants. Furthermore, the reference appears to teach that these benefits and effective concentrations for topical applications are well known for Vitamin C formulations (see cols. 1 & 2). The reference discloses that challenges have been how to formulate stable topical formulations of Vitamin C, particularly at the higher concentrations needed for maximum activity (col. 2, lines 15-20). Hence, the instant invention is rendered obvious and unpatentable over the teachings of Siddiqui.

Claims 23-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hernandez *et al.* (US Pat. No. 5,843,411).

Hernandez et al. teach a stable composition and method of treating and/or preventing photo-aged skin, sunburn, wrinkles and related skin disorders by topically applying to affected areas of the skin, the treatment composition containing an effective amount of a compound such as ascorbic acid, derivatives of ascorbic acid and/or extracts containing ascorbic acid, in a pharmaceutically acceptable vehicle containing a

substantially anhydrous base having no water added, wherein the ascorbic acid is contained in a concentration of 0.1% by weight to 95% by weight (see Abstract, column 2, lines 63-65); (col. 3, line 20 – col. 5, line 34).

According to Hernandez, the substantially anhydrous base protects the ascorbic acid, or its derivatives and/or extracts containing ascorbic acid, from degradation, instability, loss of potency and loss of color. The composition may also contain preservatives, humectants, pH buffers and carrier solvents. Certain pH buffers, such as alkaline sodium citrate and magnesium citrate and solvents may also function as a substantially anhydrous base. The resultant mixture is a smooth feeling delivery vehicle, which delivers the ascorbic acid (or its derivatives) to the skin in an effective and stable manner (col. 3, line 55 – col. 4, line 17).

Other substantially anhydrous compositions, with no water added, may be substituted for the silicones, such as other emollients, including esters, amides, ethoxylated fats, mineral oil, petrolatum, vegetable and animal fats. Substantially anhydrous synthetic waxes, such as triglycerides and tribehin may be utilized (col. 5, lines 4-12).

Hernandez states that ascorbic acid, or its derivatives, esters of ascorbic acid, amides of ascorbic acid, L-ascorbic acid, known as Vitamin C, or other derivatives or related compounds which may supply L-ascorbic acid or its derivatives, is applied in a pharmaceutically acceptable vehicle, in a concentration of from 0.1% to 95% by weight, preferably 10-15% by weight, generally by frequent periodic application, such as by a once or twice daily application (col. 4, lines 33-47).

The examples at columns 5 & 6 demonstrate topically applied skin care products comprising ascorbic acid. Moreover, Table I shows the stability of examples of the composition, using ascorbic acid, specifically L-ascorbic acid at 10%.

Hernandez does not explicitly teach the specific pH of the formulation.

However, the reference teaches that the ascorbic acid formulation is in a non-aqueous base or substantially anhydrous composition (col. 3, lines 60-67) containing silicones and derivatives of silicone chemistry (col. 4, lines 60 – col. 5, line 65). Or alternatively, an alkaline buffering agent. As such the pH of the formulation would appear to be close to neutral pH. Thereby rendering obvious the claimed invention as a whole.

Regarding the instantly claimed particle sizes, it is deemed obvious to one of ordinary skill that suitable ranges could be determined through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters. Furthermore, the prior art teaches and recognizes that L-ascorbic acid and Vitamin C are known to be effective for prevention of UV damage to the skin and act as an anti-oxidant to counteract the skin damage ranging from transitory sunburn to permanent wrinkles from photo-aged skin (col. 1, lines 24-30), wherein Hernandez et al. invented a way to stabilize ascorbic acid and the derivatives having similar utilities. Hence, the instant invention is rendered obvious and unpatentable over the teachings of Hernandez *et al.*

Claims 23-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor *et al.* (US Pat. No. 5,308,621).

Taylor *et al.* teach an ascorbic acid composition and method of treatment of a disorder in a human or animal comprising topical application of ascorbic acid by transdermal migration, whereby the composition includes fine particulate ascorbic acids suspended in a pharmaceutically acceptable carrier and wherein the ascorbic acid is present in a concentration of up to 45% by weight or up to 60% by weight of the composition (see Abstract and reference column 1, line 36 – col. 2, line 57).

According to Taylor, the ascorbic acid composition provides relief from symptoms and pain associated with rheumatoid and osteo-arthritis, soft tissue injury, various skin conditions, such as acne, urticaria, psoriasis, mullusca contagiosa, as well as symptoms and pain of sinusitis, rhinitis and hayfever. The composition may also be used to reduce or remove melanin blemishes and are suitable to be used for cosmetic purposes, such as a make-up base (col. 2, lines 44-53).

The particles of ascorbic acid have a particle size of less than 20 microns (μm). In a preferred embodiment, the solid particles are less than 15 micrometers, less than 10 μm and less than 6 μm (col. 2, lines 13-19) (instant claims require no greater than ~5(μm)).

The method of the invention may be carried out by heating the carrier to the desired temperature and then adding the ascorbic acid. Alternatively, the mixture may be produced at room temperature. The ascorbic acid can be prepared by other methods as well, such as by grinding. Carriers include glycerol (col. 3, lines 16-67).

The examples at cols. 4 & 5 demonstrate various ascorbic acid preparations and methods for preparing the same.

There is no significant distinction observed between the instant invention and the prior art since the prior art teaches the use of ascorbic acid for treating various disorders in humans and animals. Hence, the instant invention is rendered unpatentable over the teachings of Taylor *et al.*

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns
December 15, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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